Foreword

This draft guidance document is intended to provide stakeholders and the Health Canada Pest Management Regulatory Agency (PMRA) with information and guidance regarding the reconsideration-of-decision process (reconsideration process) as specified in the *Pest Control Products Act* and the proposed Review Panel Regulations. Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. This document is intended to be used in conjunction with the *Pest Control Products Act* and the proposed Review Panel Regulations. The document is not to be considered a substitute for the Act and/or the proposed Review Panel Regulations, nor should it be used as a stand-alone document.

The PMRA is soliciting comments from interested parties on this draft guidance document. The PMRA will accept written comments up to 45 days from the date of publication of this draft guidance document. Please forward all comments to Publications (contact information on the cover page of this document).

Table of Contents

1.0 The Reconsideration-of-Decision Process

The new *Pest Control Products Act* came into force on 28 June 2006. A number of provisions under the Act provide for increased transparency and public participation.

As per the new legislation, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to effect a major amendment to a registration; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or special review. Conditional registrations, granted under the new Pest Control Products Regulations, are not subject to the reconsideration of decision provisions under the *Pest Control Products Act* unless they are converted into a full registration or renewed. When a registrant applies to convert a conditional registration to full registration or to renew a conditional registration, a consultation must take place on the proposed decision and the reconsideration process applies.

Any person who believes there is a scientific basis for requesting a reconsideration of decision may file a notice of objection. Notices will be reviewed and recommendations will be forwarded to PMRA senior management to determine if there is need to obtain the advice of a panel of experts in relation to the objection. PMRA officials are duly qualified to act on behalf of the Minister of Health in accordance with the *Interpretation Act*. A review panel (panel) will be established depending:

- on whether the information in the notice raises scientific-founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pesticide; and
- on whether the advice of the expert scientists would assist in addressing the subject matter of the objection.

This document is intended to provide information and guidance regarding the reconsideration process specified in the *Pest Control Products Act* and the proposed Review Panel Regulations published in the Canada Gazette, Part I. It describes the various steps in the reconsideration process. A process map is provided in Appendix I.

2.0 Filing a Notice of Objection

A notice requesting a reconsideration of decision must include standard information such as the name of the person who is filing the objection (objector), the substantive issue(s) to which the objection relates (i.e. the health risks, environmental risks and/or value of the active ingredient and/or product) and the scientific basis for the objection. The objector is responsible for ensuring that the notice is complete and accurate. A sample form for filing an objection is attached in Appendix II.

Prior to filing any notice, the objector can apply to consult the confidential test data supporting the registration decision. If the product is registered, this confidential test data will be available for public inspection in the Reading Room. The PMRA places a higher priority on applications to inspect data associated with a recent regulatory decision for which the 60-day reconsideration period is still open. As the time frame to submit a notice is established by legislation, applications to inspect the confidential test data in question should be received well in advance of the closing date of the reconsideration period for processing if the intention is to consider submitting a notice. Further details for accessing the confidential test data are provided on the PMRA's website.

Where an objector refers to information such as scientific reports or confidential test data to provide evidence for the notice, the objector should include this information as part of the scientific basis of the objection. The objector should also explain how the information in the notice raises scientifically founded doubt as to the validity of the evaluations on which the decision was based. Where the scientific information provided is new information (e.g. a new epidemiology study), the information will be reviewed to determine its admissibility in the reconsideration process. The information provided may instead be subjected to other kinds of review (e.g. special review) rather than a review panel examination. It is important to note that the reconsideration process is not an opportunity to add to the content of the original submission (e.g. the addition of a new use) or to circumvent established processes for amending registrations.

Individuals submitting an objection must also provide some personal information prescribed by the proposed Review Panel Regulations and defined in the *Privacy Act* (e.g. name, address). This personal information may be made public as authorized by the *Pest Control Products Act* and its Regulations for the purpose of the reconsideration process.

2.1 Reviewing a Notice of Objection

All notices will be reviewed once the 60-day filing period has ended. The objector is responsible for ensuring the information provided to the PMRA is complete; normally, there will be no additional opportunity to file additional objections or amend a submitted objection.

2.1.1 Recommendations to Establish a Panel

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

2.1.2 Criteria for Establishing a Review Panel

The decision whether to establish a panel must be made on the merits of the case presented by the objector who filed the notice. In general, the following criteria will be considered in determining whether to establish a panel:

- whether the information in the notice raises doubt as to the interpretation of the scientific information, on which the decision was based;
- whether the information in the notice raises any disagreements as to the applied methodology of the scientific information, on which the decision was based;
- whether the information in the notice raises concern(s) as to the relative weights given to data impacting on the risk assessment of the scientific information, on which the decision was based;
- whether the information in the notice raises concern(s) regarding the conclusion reached during the decision making process;
- whether the advice of one or more expert scientists would be useful and appropriate in responding to the issue(s) identified in the notice; and
- whether the Minister has not already received such above noted advice.

Objections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a panel. Providing knowingly false or misleading information to a review panel is an offence under the *Pest Control Products Act* and may be subject to prosecution.

2.2 Notice to Establish a Review Panel

When it is determined that the objection has merit and advice of scientific expert(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and the affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review or until the panel is dissolved.

Where a request to reconsider a registration decision is refused, the reasons for refusa will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

2.3 Terms of Reference for Review Panels

The PMRA will determine the terms of reference (ToR) that will establish the panel's mandate and provide guidance to persons interested in making representations by identifying the specific issues(s) that the panel will consider. The ToR will require that the panel focus on the review of science and the review be limited to issue(s) that can be properly dealt with by persons with scientific expertise without relying on persons trained in law. The ToR will also suggest target timelines for the panel procedures and may require a detailed workplan on how the milestones will be achieved and regular status updates for tracking purposes. The ToR will be made available in the Public Registry on the PMRA's website. Any requests for revision to the ToR must be submitted to the PMRA for consideration.

2.4 Establishing Review Panels

Without undue delay, the PMRA will contact potential panel members who have expertise relevant to the ToR and examine their credentials (e.g. professional credentials, educational background). Panel members will be required to possess scientific knowledge and be capable of evaluating and assessing objectively the representations made to the panel by interested parties who participate in the review. The PMRA will select as many experts as are needed to evaluate and assess the representations. All panel members will also be required to meet conflict of interest and security clearance requirements. Any person who was involved with decisions related to the registration decision will not be eligible to become a panel member. Each panel member will be paid travel and living expenses in accordance with applicable Treasury Board of Canada directives.

2.4.1 Removal of Panel Members

Panel members that are unable to perform their duties can be removed. Members can also be removed if a conflict of interest arises or if a member requests to be removed from the panel for other reasons. Another qualified person shall be selected to replace a member unless the review can be properly completed by the remaining members.

2.5 Review Panel Proceedings

The panel is responsible for determining the acceptability of the request(s) to make a representation and the admissibility of evidence based on whether they are relevant to the ToR. In all cases, the panel will advise the person(s) who made the request(s) of its decision and the reasons for accepting or refusing the request(s), or portions thereof.

If it will not impair anyone's ability to participate effectively in a hearing, the chairperson may allow teleconferencing or videoconferencing equipment to be used to make representations. A panel may also conduct any or all of the review using documentary submissions only.

All participants, other than panel members, are responsible for the costs of participating in the hearings.

2.5.1 Admissibility of Evidence

The panel may receive and accept any evidence or information it considers relevant to its mandate, regardless of its admissibility in a court of law. The conduct of the review will not be hampered by judicial rules of evidence or procedure. The panel has the authority to determine what information is relevant to the ToR, the level of credibility of the information and what weight to give to it. In addition, the panel may request and receive information and advice from persons who have not made an application to participate in the hearings.

2.5.2 Consideration of Confidential Information

Panel members and participants in a hearing will have access to confidential information that is in the Register. They are required to take all reasonable precautions to avoid any prohibited disclosures of the information. The review panel hearings will be closed to the public when confidential information is being discussed to prevent public disclosure. Participants making representations are responsible for notifying the panel in advance if they wish to discuss confidential information at the hearing. The panel will note items of the hearing agenda that are restricted to panel members and participants only.

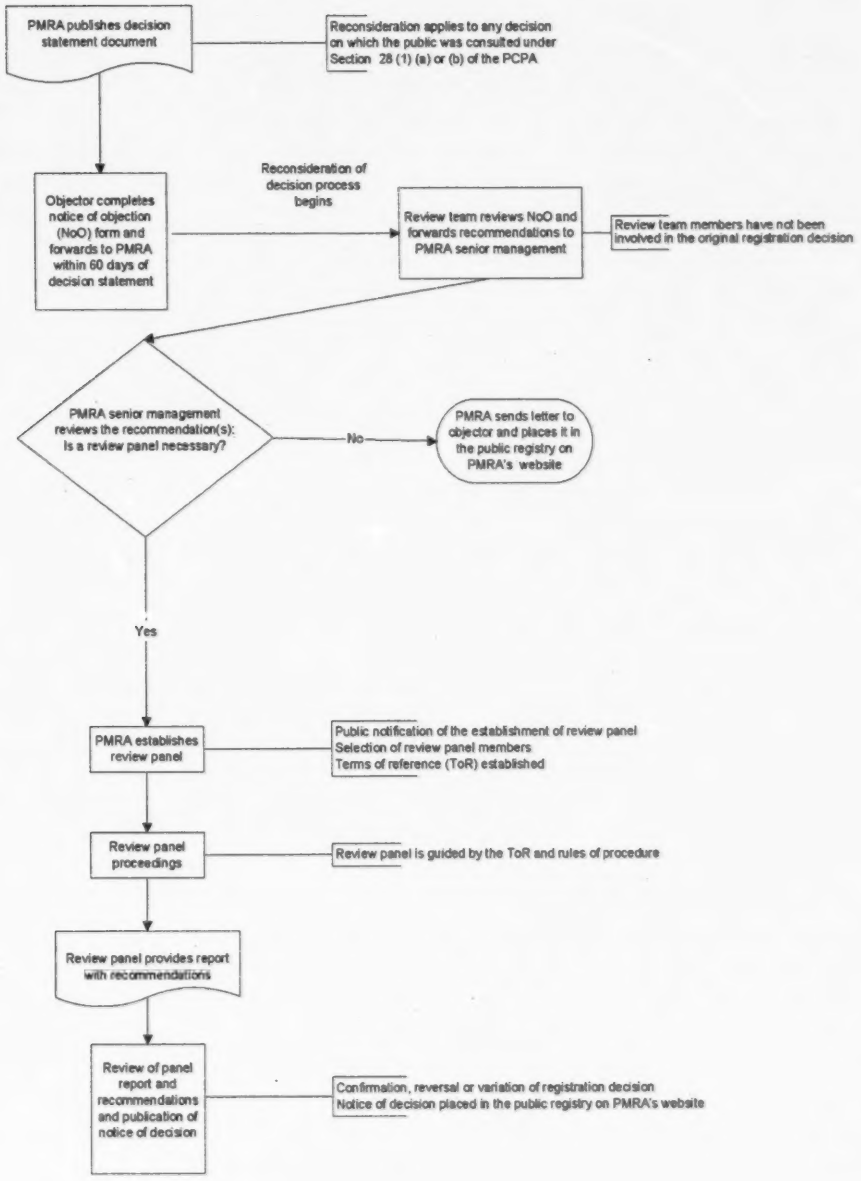
To access confidential information that is not in the Register, participants must submit a request to the panel in the form of a sworn affidavit or statutory declaration. Requests must contain an undertaking not to disclose the information or data to any other person and not to use it for any purpose other than for participation in the hearing. Only the hearing participants who have satisfied the access request requirements will be permitted to be present at such hearings.

3.0 Review Panel Report and the PMRA's Final Decision

At the conclusion of its review, the panel will provide a report to the PMRA without undue delay. The report will contain its findings, analysis and recommendation(s). It will summarize the evidence and the arguments and provide an assessment, indicating where the panel agrees and disagrees with the presentations. If the panel is unable to reach unanimity on a recommendation, the panel's report will document the differences of position of the panel members. Recommendations provided by the panel to the Minister are not binding. The panel's report will be placed in the Public Registry on the PMRA's website.

Once the panel report is submitted, the PMRA may request clarification from the panel members with respect to specific recommendations. The PMRA's confirmation, reversal or variation of the registration decision (e.g. an amendment to a label), along with the reasons and summary of the information considered, will be made available in the Public Registry on the PMRA's website. No further opportunity for formal consultation on the confirmation, reversal or variation of the PMRA's decision will follow the reconsideration of a decision. In taking the final decision, the same scientific standards will be applied as during the registration process.

Appendix I Reconsideration-of-Decision Process Map



Appendix II Notice of Objection Form

Health Canada / Santé Canada
Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

Date Received / Date de réception :

Office Use Only / à usage interne seulement

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la *Loi sur les produits antiparasitaires*

1. Objector information - Information sur l'opposant

Name - Nom / Corporation - société / Organization - organisation

Postal Address - Adresse postale

City/Town - Ville	Province/State - Province/État	Country - Pays	Postal Code/ZIP - Code postal/Zip

Phone - Téléphone	Fax - Télécopieur	E-mail - Adresse électronique

2. Product information - Information sur le produit

Name of active ingredient to which the decision relates:
Nom de la matière active à laquelle la décision se rapporte :

Name of end-use product to which the decision relates:
Nom de la préparation commerciale à laquelle la décision se rapporte :

3. Registration decision to which the objection relates -
Décision d'homologation pour laquelle vous déposez un avis d'opposition

Decisions on application - Décision concernant la demande

- ☐ Granting registration - Homologation accordée
- ☐ Denying registration - Homologation rejetée
- ☐ Granting an amendment of a registration - Modification à l'homologation accordée
- ☐ Denying an amendment of a registration - Modification à l'homologation rejetée

Decisions on re-evaluation or special review - Décision concernant la réévaluation ou l'examen spécial

- ☐ Confirming registration - Homologation confirmée
- ☐ Cancelling registration - Homologation annulée
- ☐ Amending registration - Modification à une homologation

4. Date the decision statement was made public:
Date de la publication de l'énoncé de décision :

5. Area of scientific evaluation to which the objection relates - Volet de l'évaluation scientifique touché par l'avis d'opposition

- ☐ Health risk assessment (toxicology, food residue, occupational exposure) -
  Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- ☐ Environmental risk assessment (environmental fate, environmental toxicology) -
  Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)
- ☐ Value and efficacy assessments (crop tolerance, value) -
  Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection *Attachment included:* ☐Yes ☐No
Fondement scientifique de l'opposition *Pièce jointe incluse :* ☐Oui ☐Non

7. Signature of objector or representative -
Signature de l'opposant ou de son représentant

Printed Name - Nom en lettres moulées

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Information required to process the notice of objection may include some personal information as defined in the *Privacy Act*. In accordance with that Act, such personal information may be made public as authorized by the *Pest Control Products Act* and its regulations. Under the *Privacy Act*, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at pmra_infoserv@hc-sc.gc.ca.

Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.

L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la *Loi sur la protection des renseignements personnels*. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la *Loi sur les produits antiparasitaires* et son Règlement. En vertu de la *Loi sur la protection des renseignements personnels*, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à pmra_infoserv@hc-sc.gc.ca.

PMRA/ARLA 7004 (2007/07)

Canada

Guidance for Completing the Application to File a Notice of Objection

Type or print clearly
Leave shaded areas blank

1. **Objector information:**
The person identified on the form will be the one to file the notice of objection. If you are not the objector and are filing a notice of objection as a representative of a corporation or an organization, please identify yourself, state the corporation or organization you represent and provide the corporation or organization information.

2. **Product information:**
Identify the active ingredient or the end-use product to which the decision relates.

3. **Registration decision to which the objection relates:**
Indicate the registration decision to which the objection relates. Specify whether the objection relates to the granting or denying of a registration of a new active ingredient or end-use product or a registration amendment. If the objection relates to a decision made following a re-evaluation or special review, specify whether it relates to the confirmation or cancellation or amendment of a registration. Notices of objection are only applicable to decisions published in a decision statement.

4. **Decision statement date:**
Indicate the date printed on the cover page of the decision statement document. A notice of objection must be filed with all required information within 60 days from the date of publication of the decision statement.

5. **Area of scientific evaluation to which the objection relates:**
Identify the science area(s) to which the objection relates. For objections related to human health risk, specify toxicology, food residue, or occupational exposure. For environmental risks, specify environmental fate or environmental toxicology and for efficacy, specify crop tolerance or value.

6. **Scientific basis for the objection:**
This section must include evidence and an explanation on how the evidence raises scientifically founded doubt as to the validity of the evaluations on which the decision was based.

Anyone wishing to inspect confidential test data for a registered product to which an objection relates should refer to the PMRA website on inspecting confidential test data, www.pmra-arla.gc.ca/english/pubreg/testdata-e.html

With any attachment submitted, please indicate on each page your name and the active ingredient, or the end-use product to which the notice of objection relates and ensure that each page is numbered.

7. **Signature of objector or representative:**
The signature must match the name of the objector or representative identified in the objector's information section.

Note: A notice of objection may contain more than one basis of objection. Only one notice of objection per objector per decision statement will be accepted for consideration. A notice of objection that is incomplete may be returned to the objector and not considered further.

Submit the notice of objection form to:

Health Canada Pest Management Regulatory Agency
Address Locator: 6606E
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Information required to process the notice of objection may include some personal information as defined in the *Privacy Act*. In accordance with that Act, such personal information may be made public as authorized by the *Pest Control Products Act* and its regulations. Under the *Privacy Act*, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at pmra_infoserv@hc-sc.gc.ca.

Health Canada / Santé Canada
PMRA/ARLA 7004 (2007/07)

Guide pour remplir le Dépôt d'un avis d'opposition

Taper ou écrire clairement en lettres moulées
Ne pas remplir les zones ombragées

1. **Information sur l'opposant :**
La personne identifiée sur le formulaire sera celle qui déposera l'avis d'opposition. Si vous n'êtes pas l'opposant et remplissez l'avis d'opposition à titre de représentant d'une société ou d'une organisation, veuillez inscrire votre nom, identifier la société ou l'organisation que vous représentez et fournir les renseignements pertinents.

2. **Information sur le produit :**
Identifier la matière active ou la préparation commerciale à laquelle se rapporte la décision d'homologation.

3. **Décision d'homologation pour laquelle vous déposez un avis d'opposition :**
Indiquer la décision d'homologation pour laquelle vous déposez un avis d'opposition. Préciser si l'opposition vise l'acceptation ou le refus d'homologation d'une nouvelle matière active ou d'une préparation commerciale ou d'une modification à une homologation. Si l'opposition est liée à une décision prise à la suite d'une réévaluation ou d'un examen spécial, préciser si elle vise la confirmation, l'annulation ou la modification d'une homologation. Les avis d'opposition sont seulement applicables aux décisions publiées dans un énoncé de décision.

4. **Date de la publication de l'énoncé de décision :**
Indiquer la date imprimée sur la page couverture de l'énoncé de décision. Un avis d'opposition doit être rempli avec tous les renseignements requis au plus tard 60 jours suivant la date de la publication de l'énoncé de décision.

5. **Volet de l'évaluation scientifique touché par l'avis d'opposition :**
Identifier le volet scientifique pour lequel l'opposition a été déposée. Dans le cas des oppositions touchant les risques pour la santé humaine, préciser s'il s'agit des données toxicologiques, de celles sur les résidus alimentaires ou de celles sur l'exposition professionnelle. Dans le cas des oppositions touchant les risques pour l'environnement, préciser s'il s'agit des données sur le devenir dans l'environnement ou sur les effets écotoxicologiques. Dans le cas des oppositions touchant l'efficacité, préciser s'il s'agit des données concernant la tolérance des cultures ou la valeur.

6. **Fondement scientifique de l'opposition :**
Cette section doit comprendre des éléments de preuve et une explication sur la façon dont ces éléments mettent en doute la validité scientifique des évaluations qui ont servi de fondement à la décision.

Toute personne désireuse de consulter des données d'essai confidentielles concernant un produit antiparasitaire au sujet duquel un avis d'opposition a été déposé devrait se reporter à la section du site Web de l'ARLA relative à la consultation de ce type de renseignements : www.pmra-arla.gc.ca/francais/pubreg/testdata-f.html

Veuillez indiquer sur chaque page de toute pièce jointe soumise votre nom et celui de la matière active ou de la préparation commerciale pour laquelle l'avis d'opposition a été déposé et assurez-vous que toutes les pages soumises sont numérotées.

7. **Signature de l'opposant ou de son représentant :**
La signature doit correspondre au nom de l'opposant ou de son représentant tel qu'identifié dans la section de l'information sur l'opposant.

Note : Un avis d'opposition peut contenir plus d'une raison pour s'objecter. On n'acceptera d'examiner qu'un seul avis d'opposition par opposant, et ce, par énoncé de décision. Un avis d'opposition incomplet peut être retourné à l'opposant et ne sera donc pas considéré.

Veuillez soumettre le formulaire d'avis d'opposition à :

Agence de réglementation de la lutte antiparasitaire de Santé Canada
Indice d'adresse : 6606E
2720, promenade Riverside
Ottawa (Ontario) K1A 0K9

Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.

L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la *Loi sur la protection des renseignements personnels*. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la *Loi sur les produits antiparasitaires* et son Règlement. En vertu de la *Loi sur la protection des renseignements personnels*, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à pmra_infoserv@hc-sc.gc.ca.

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